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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,043	01/19/2001	Scot R. Shepard	D/2001.690 US PD	9618
31846	7590	10/16/2006	EXAMINER	
INTERVET INC. PATENT DEPARTMENT PO BOX 318 MILLSBORO, DE 19966-0318			MOHAMED, ABDEL A	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/766,043

Applicant(s)

SHEPARD, SCOT R.

Examiner

Abdel A. Mohamed

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 7/15/02, 4/2/04.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF IDS, STATUS OF THE APPLICATION AND CLAIMS

1. The Information Disclosure Statements (IDS) and Form PTO-1449 filed 07/15/02 and 04/02/04, respectively are acknowledged, entered and considered. Claims 1-14 are present for examination.

ABSTRACT IS MISSING

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

OBJECTIONS TO TRADEMARKS AND THEIR USE

3. The use of trademark "Y-PER®" has been noted in this application. Although, the use of trademark is permissible in patent applications, the proprietary nature of the mark should be respected and every effort made to prevent its use in a manner, which might adversely affect their validity as trademark.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description is inherent in the article referred by the trademark. This description requirement is made because the nature and composition of articles denoted by trademark can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 112^{1st} PARAGRAPH

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 and claim depending thereof (i.e., claim 7) as original filed contains new matter because the original specification does not appear to support "a detergent comprising a final concentration of between 0.01 to 10 percent". The instant specification on page 3, second paragraph and page 10, last paragraph states that detergents may be used at concentrations ranging from 0.01% up to their solubility limit, preferably the concentration of the detergents ranges from 0.05% to 5%, 0.1% to 2%, or is approximately 0.5% of the total solution. Thus, claim 5 and dependent claim thereof (i.e., claim 7) have no support for the limitations "a detergent comprising a final concentration of between 0.01 to 10 percent" from the original disclosure because there is no disclosure in the specification as now claimed. Thus, Applicant respectfully

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requested to either cancel all unsupported subject matter or to show where such subject matter has support from the original disclosure.

HEADING FOR NONSTATUTORY DOUBLE PATENTING

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

6. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,821,752. Although, the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention (Serial No. 09/766,043) as claimed in claims 1-14 is directed to a process of releasing a protein from a cell by contacting a host cell containing a protein of interest with a solution comprising one or more detergents having various concentrations and incubating the host cells and detergent mixture at a temperature of between about 3 °C and about 10 °C. Similarly, claims 1-17 of '752 patent is directed to a process of releasing a protein from a cell by contacting a host cell containing a protein of interest with a solution comprising one or more detergents and one or more reducing agents having various concentrations and incubating the host cells and detergent mixture at a temperature of between about 2 °C and about 50 °C.

Thus, both inventions use the same procedure/process and components for a method of releasing a protein of interest from host cells. Hence, both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the '752 patent claims and the claims of the instant application is the scope of the claims in which the application claims appear to be specific in scope because there are no specific reducing agents and specific pHs, although, the ranges of the temperatures for incubation overlap in ranges in both sets of claims (See e.g., claim 14 of the instant specification and claim 5 of '752 patent). Thus,

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the selection of appropriate pHs and specific reducing agents for the intended purposes of facilitating the recovery of proteins would be conventional and within the ordinary skill in the art to which this invention pertains. Further, the limitations of claims 2, 3, 7, 10 and 12 of the instant application is substantially identical with the limitations of claims 2, 3, 17, 4 and 10, respectively of '752 patent. Furthermore, the glycerol concentrations of claim 6 and 7 of the instant application overlaps with the concentration ranges claimed in claim 15 of '752 patent.

Therefore, since both inventions are directed to a process of recovering intracellular proteins and other molecules from host cells in a large-scale production wherein the host cells are particularly *Pichia pastoris* cells. Thus, both inventions use substantially the same processes and components for the same purpose; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for the same purposes.

Therefore, both inventions (i.e., both sets of claims) are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

CONCLUSION AND FUTURE CORRESPONDANCE

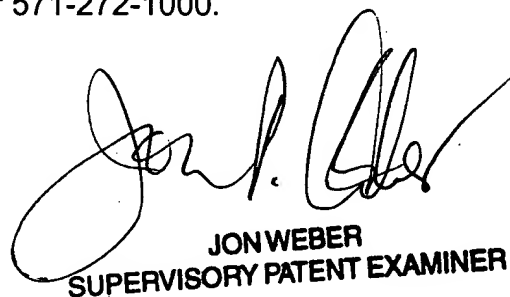
7. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON WEBER
SUPERVISORY PATENT EXAMINER

AM Mohamed/AAM
September 28, 2006